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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,381	09/21/2005	David Aitken	PN/4-33001A	3366

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
ZAREK, PAUL E	

ART UNIT	PAPER NUMBER
1617	

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04/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,381	AITKEN ET AL.	
	Examiner	Art Unit	
	Paul Zarek	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,6,7,9,10 and 13* is/are pending in the application.

4a) Of the above claim(s) _9_ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,6,7,10 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/17/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claim 1 has been amended and Claims 3-5 have been cancelled by the Applicant in correspondence filed on 02/11/2009. Claims 1, 2, 6, 7, 9, 10, and 13 are currently pending. Claim 9 remains withdrawn as being drawn to a nonelected invention. Claims 1, 2, 6, 7, 10, and 13 are examined herein. This is the second Office Action on the merits of the claim(s).

RESPONSE TO ARGUMENTS

2. Examiner acknowledges IDS files on 02/17/2009. This IDS fails to comply with 37 CFR 1.98(a)(2). Specifically, Mutschler, et al., in not in English, and Beers and Berkow, Zamnowski, et al., and Borowicz, et al. (2001), have not been supplied. The IDS has been placed in the application file, but the information of the above-mentioned documents has not been considered.

3. Claims 1-7, 10, and 13 were rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements. This rejection is moot in light of Applicants' amendment to Claim 1.

4. Claims 1-7 were rejected under 35 U.S.C. 103(a) as being unpatentable over Czuczwar, et al. (European Journal of Pharmacology, 1998), in view of Deckers (CNS Drugs, 2002), and Suter, et al. (Mutation Research, 2002). Claims 1-7, and 10 were rejected under 35 U.S.C. 103(a) as being unpatentable over Levy, et al. (US Patent No. 5,095,033, 1992) in view of Deckers and Suter, et al. Applicants traversed these rejections on the grounds that the combinations of Czuczwar, et al., Deckers, and Suter, et al., or Levy, et al., Deckers, and Suter,

et al., do not teach or fairly suggest the claimed invention. Specifically, Applicants assert two points: 1) that neither Czuczwar, et al., nor Levy, et al., provide a motivation to substitute LY300164 (Czuczwar, et al.) or stiripentol (Levy, et al.) with AMP397, the elected species; and, 2) the combination of carbamazepine and AMP397 produced "unexpectedly superior results." Examiner respectfully disagrees.

5. Czuczwar, et al., and Levy, et al., teach that: A) carbamazepine is an effective anti-epileptic medicament; and, B) carbamazepine can be administered along with an additional anti-epileptic medication. Suter, et al., teach that the elected species, AMP397, is a known AMPA receptor antagonist, and a potent anti-convulsant. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (MPEP § 2144.06(I). Deckers teaches that both sequential monotherapy and polytherapy are good options for the treatment of epilepsy (pg 162, section 5 "Conclusions"), indicating that anti-epileptic drug combinations (simultaneous, sequential or separate) are well known in the art. Deckers also teaches that when adding a second anti-epileptic to a treatment regimen, it is advantageous to choose a drug with a different mechanism of action than the first (pg 162, section 4.3). This provides motivation to combine carbamazepine and AMP397, whose mechanisms of action are known to be independent of each other.

6. In light of Decker, which teaches that the optimal combination of anti-epileptics is one in which the components have differing mechanisms of action, it is unclear by which metric the

results disclosed in Table 1 are unexpectedly superior over the prior art. Table 1 demonstrates that either 7.5 mg/kg carbamazepine or Compound **1** (AMP397), alone, does not protect mice from seizures. The combination of carbamazepine and Compound **1** protected 40% of the mice from seizures. Likewise, Czuczwar, et al., demonstrates that 2 mg/kg LY300164 alone offers no protection from seizures (Fig 1). However, when the presence of 2 mg/kg LY300164 significantly lowered the ED_{50} of carbamazepine. Furthermore, nowhere in the instant specification do Applicants claim that the results disclosed in Table 1 are unexpected. One of ordinary skill in the art would have reasonably expected AMP397, a known AMPA receptor antagonist to potentiate the anti-convulsant effect of carbamazepine. "[A] greater than additive effect is not necessarily sufficient to overcome a *prima facie* case of obviousness because such an effect can either be expected or unexpected. Applicants must further show that the results were greater than those which would have been expected from the prior art to an unobvious extent, and that the results are of a significant, practical advantage. *Ex parte The NutraSweet Co.*, 19 USPQ2d 1586 (Bd. Pat. App. & Inter. 1991)" (MPEP § 716.02(a)(I)). Therefore, the rejections of Claims 1-7 under 35 U.S.C. 103(a) as being unpatentable over Czuczwar, et al., in view of Deckers, and Suter, et al., and Claims 1-7, and 10 under 35 U.S.C. 103(a) as being unpatentable over Levy, et al., in view of Deckers and Suter, et al., are maintained.

7. Claim 13 was rejected under 35 U.S.C. 103(a) as being unpatentable over Czuczwar, et al., and Deckers and Suter, et al., as applied to claims 1-7 above, and further in view of Weaver, et al. (US Patent No. 6,306,909, 2001). Applicant traversed this rejection on the grounds that Czuczwar, et al., Deckers, and Suter, et al., did not fairly teach or suggest combining carbamazepine and AMP397. Applicants have not disagreed with Weaver, et al., in the manner

in which it was applied to Claim 13 (namely, with respect to putting anti-epileptic medicaments in a kit). Examiner disagrees for the reasons set for above. Therefore, the rejection of Claim 13 under 35 U.S.C. 103(a) as being unpatentable over Czuczwar, et al., Deckers, and Suter, et al., further in view of Weaver, et al., is maintained.

Amended Claims 1, 2, 6, 7, 10, and 13 are examined on their merits and the following **FINAL** rejection is made.

Claim Rejections - 35 USC § 112 (2nd paragraph)

8. The text of Title 35, U.S.C. § 112, second paragraph, can be found in a prior Office action.

9. Claims 6 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 6 and 7 recites the limitation "according to claim 5" in line 1. There is insufficient antecedent basis for this limitation in the claim because Claim 5 has been cancelled by Applicants.

Conclusion

10. Claims 1, 2, 6, 7, 10, and 13 remain rejected.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Zarek whose telephone number is (571) 270-5754. The examiner can normally be reached on Monday-Thursday, 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PEZ

/Rita J. Desai/
Primary Examiner, Art Unit 1625